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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IMPAX LABORATORIES, INC.,

Plaintiff,

v.

MEDICIS PHARMACEUTICAL CORP.,

Defendant.

CASE NO.: C08-0253-MMC

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MEDICIS'S MOTION TO DISMISS

Date: April 11, 2008
Time: 9:00 a.m.
Before: Hon. Maxine M. Chesney

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I. INTRODUCTION

To protect its Solodyn® franchise, Medicis has endeavored to "send a very strong message" to generic competitors that they will be sued for patent infringement. It has developed concrete plans to "aggressively" enforce the patent-in-suit and has lined up "vicious" attorneys who are prepared to do so. As a consequence, a generic competitor of Solodyn® faces a real and immediate threat of suit.

Impax is one (and the only known) such generic competitor. It has submitted an Abbreviated New Drug Application (ANDA) to market a generic version of Solodyn.® Because submission of an ANDA may constitute an act of infringement, Impax is presently faced with the specter of a patent infringement suit. Under the Declaratory Judgment Act, Impax need not sit idly by and wait to be sued. Rather, it is entitled to clear the air of the uncertainty and insecurity created by charges of patent infringement.

Medicis's unrelenting threats of patent infringement litigation were no doubt intended to have a tangible impact on generic competitors of Solodyn.® And indeed they have. Impax proceeds with its ANDA knowing that it may be sued for patent infringement at any time. This creates a cloud of uncertainty over its ANDA application. The resources expended on drug development and bioequivalence studies required for the ANDA and the ongoing efforts to obtain regulatory approval may be for naught. Ultimately, Impax's ability to secure approval of its ANDA is threatened.

Impax does not seek an advisory opinion. It has tangible interests at stake that are directly impacted by Medicis's threats to sue for patent infringement. Medicis's calculated decision to delay bringing suit is of no moment. The Declaratory Judgment Act was intended to allow the courts to resolve such disputes where the parties have adverse legal interests. It is properly utilized to do so here.

II. FACTUAL BACKGROUND

A. The Parties and the Patent-in-Suit

Medicis sells Solodyn,® an extended release form of the antibiotic minocycline. Medicis asserts that the use of Solodyn® is covered by U.S. Patent 5,908,838 ("the '838 patent")

(Compl. ¶ 9; Ex.[1] E at 2), even though minocycline is an old antibiotic that has been known for decades. It is Medicis's publicly-stated intention to sue generic competitors of Solodyn® for infringement of the '838 patent. (Compl. ¶¶ 10-11.)

Impax is a pharmaceutical company that specializes in developing controlled-release drug formulations. It concluded that its generic version of Solodyn® is not covered by any valid claims of the '838 patent. Impax thus submitted an ANDA with the FDA, seeking approval to market a generic version of Solodyn®. (Compl. ¶ 7; Ex. A.) This ANDA procedure was created by the Hatch-Waxman Act[2] in order to create price competition and encourage generic manufacturers such as Impax to challenge invalid patents. *See Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 29 (D.D.C. 2006), *aff'd*, 2006 WL 2591087 (D.C. Cir. Aug. 30, 2006).

In order to resolve the dispute regarding the '838 patent, Impax brought this action for a declaratory judgment that it does not infringe any valid claims of the '838 patent.

B. Medicis's Threats of Suing Generic Competitors for Patent Infringement

According to Medicis, Solodyn® is its largest seller and "flagship product." (Ex. J at 2.) Thus, Medicis considers it to be "imperative for our company" to preserve its monopoly position with respect to this product. (Ex. K at 3.) As Medicis explained to its investors: "So, I think you can be sure that in every conceivable respect, we are attempting to protect Solodyn®." (*Id.*) Its goal for the Solodyn® franchise is "keeping it alive as long as we possibly can." (Ex. M at 3.)

Medicis's strategy to protect its flagship Solodyn® product turns on the '838 patent. It claims that the use of Solodyn® is covered by the '838 patent. (Ex. E at 2; Ex. L at 10.) Indeed, Medicis has gone so far as to mark the Prescribing Information for Solodyn® with the '838 patent (Ex. D at 2 (col. 3)), thereby conveying its stance that the '838 patent covers the use of Solodyn® and putting competitors on notice of its claim. 35 U.S.C. §§ 287(a) & 292.

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[1] "Ex." refers to the corresponding exhibit to the Declaration of Roger J. Chin in Support of Impax's Opposition to Medicis's Motion to Dismiss, filed concurrently herewith. On a motion to dismiss for lack of jurisdiction, the Court may consider evidence outside of the pleadings. *FDIC v. Nichols*, 885 F.2d 633, 635-36 (9th Cir. 1989).

[2] Formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Medicis asserts that if a generic competitor launches a competing product to Solodyn,® it faces "the risk of a suit for patent infringement" under the '838 patent.[3] (Ex. B at 42 (emphasis added); *see also* Ex. C at 15.)

Medicis takes steps to ensure that generic competitors know that the "risk of a suit for patent infringement" is real. Jonah Shacknai, Medicis's CEO, explained this strategy:

> If [generic competitors of Solodyn®] willfully infringe them there are very significant damages, treble damages. We're going to be very vigorous I think in enforcing the patents or even the suggestion that someone is going to infringe our patents. We've employed several different law firms, not only to review what we have, but also to plan what we will have. And we have hired a couple of firms that I think are vicious in their enforcement and protection of patents, because we want to send a very strong message that this needs to be an impenetrable defense around this brand.

(Ex. F at 13 (emphasis added).) Pointing to the "generic companies [that] have eyed this [Solodyn®] market," Mr. Shacknai emphasized that "[w]e intend to enforce with the ultimate vigor the patents that have issued" (Ex. G at 3) – the only such patent that has issued being the '838 patent. (Ex. B at 42; Ex. E at 2.) Medicis's Vice President of Corporate and Product Development, Joseph Cooper, added that Medicis will be proactive in enforcing the '838 patent in court against generic competitors of Solodyn® and will "aggressively prosecute the patents, go after preliminary injunctions to ward off any infringers." (Ex. I at 6 (emphasis added).) Medicis's plan is to "put relevant parties on notice about potential infringement" and "the vigorous approach that we would take to enforcing the patent." (Ex. H at 6.)

These are not just idle threats. Medicis has already implemented a "very aggressive defensive strategy from a legal point of view" against generic competitors and is "ready for challenges that may occur . . . with some of the finest lawyers that are available in the United States." (Ex. K at 3.) It has "employed several different law firms" that "are vicious in their enforcement and protection of patents." (Ex. F at 13.) With this strategy in place, Medicis is "confident that we can protect" Solodyn® against potential generic challenges. (Ex. L at 10.)

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[3] While Medicis did not identify the allegedly infringed patent by number, the context of this statement clearly concerned the '838 patent. The statement referred to "patent coverage for Solodyn® [that] does not expire until 2018." (Ex. B at 42.) The '838 patent expires in 2018, and Medicis does not hold any other issued patents relating to Solodyn.® (*Id.*)

C. Impax's Attempts to Resolve the Patent Dispute

In 2007, Impax submitted an ANDA, seeking approval from the FDA to commercially manufacture and sell a generic version of Solodyn®. (Compl. ¶ 7.) Consistent with the relevant statutory requirements, *see* 21 U.S.C. § 355(j)(2)(A), this generic product is bioequivalent to Solodyn®, having the same active ingredient, route of administration, dosage form, and strength. (Compl. ¶ 8.)

Impax was aware of Medicis's public assertions that a generic competitor of Solodyn® faces "the risk of a suit for patent infringement." (Ex. B at 42.) Thus, in December 2007, Impax notified Medicis of its ANDA submission and its conclusion that the generic version of Solodyn® for which Impax sought approval was not covered by any valid claims of the '838 patent. (Ex. A.) In order to allow Medicis to draw its own conclusions on this issue, Impax offered access to its confidential ANDA submission.[4] (Ex. A.) Finally, Impax requested that Medicis provide a covenant not to sue under the '838 patent, in an effort to dispel the dispute created by Medicis's assertions about the "risk of a suit for patent infringement." (*Id.*) Impax's Offer of Confidential Access was valid so long as Medicis returned a signed copy of that confidentiality agreement within two weeks. (*Id.*)

Medicis did not (and to date has failed to) grant Impax's requested covenant not to sue. (Compl. ¶ 12.) Nor did Medicis respond by the time the confidentiality agreement expired. But while Medicis was supposedly too busy or too distracted to respond to Impax's letter (*see* Mot. at 4 n.1), it had plenty of time to tell the rest of the world of its plans. During this time, even after Impax informed Medicis of its generic version of Solodyn,® Medicis continued to boast that it will pursue its generic competitors with "extreme aggression." (Smolenski Decl.[5] ¶ 3; *see also* Ex. C at 15.)

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[4] Impax offered this information under an "Offer of Confidential Access" modeled on statutory provisions applicable to other types of ANDAs, where such access is provided in order to allow a patentee sufficient information to determine whether an action for patent infringement should be brought. *Compare* Ex. A *with* 21 U.S.C. § 355(j)(5)(C)(i)(III).

[5] "Smolenski Decl." refers to the Declaration of Ted Smolenski in Support of Impax's Opposition to Medicis's Motion to Dismiss, filed concurrently herewith.

III. ARGUMENT

A. There Is an Actual Controversy Between Impax and Medicis Concerning Alleged Infringement of the '838 Patent

1. Legal Standards

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Patent litigation "is particularly adapted to declaratory resolution." *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1357 (Fed. Cir. 2004).

The recent Supreme Court case of *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), established "more lenient legal standard[s]" for "the availability of declaratory judgment jurisdiction in patent cases." *Micron Tech., Inc. v. MOSAID Techs., Inc.*, __ F.3d __, 2008 WL 540182, at *4 (Fed. Cir. Feb. 29, 2008). Under *MedImmune*, an action for declaratory relief under the Declaratory Judgment Act satisfies the "case or controversy" requirement of Article III if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 127 S. Ct. at 771 (citations omitted)

A party may seek declaratory relief to clear the air and resolve its potential patent infringement liability. It need not wait to be sued. When a patentee asserts rights under a patent based on certain planned activity of another party, and where that party contends that it has the right to engage in the accused activity, an Article III case or controversy exists under the Declaratory Judgment Act. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

2. Impax's ANDA Submission Creates a Justiciable Infringement Controversy

By submitting an ANDA and seeking FDA approval for a generic version of Solodyn®, Impax is presently subject to a claim for infringement of a patent that covers the drug:

> It shall be an act of infringement to submit an [ANDA] application . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). Medicis acknowledges that Impax's ANDA submission gives rise to an actionable claim of infringement under this provision. (Mot. at 6 ("an ANDA filing is a 'technical' act of infringement").)

Congress may, by legislation, create legal rights that form the basis for standing and injury-in-fact under Article III. *Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n.3 (1973) ("Congress may enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute"). That is exactly what Congress did when it passed Section 271(e)(2) and the Declaratory Judgment Act. Where an ANDA is filed, Section 271(e)(2) provides "patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added); *see also Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) ("The very act of submitting an ANDA is an act of infringement. . . . There is no question that under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA. . . .").

While Medicis admits that it may presently sue Impax, it attempts to carve out an exception based on Solodyn®'s status as an "old antibiotic" to justify an asymmetric rule whereby Impax would be prohibited from bringing a declaratory judgment action. (Mot. at 3-4.) Medicis is mistaken. The basis of the controversy – Medicis's present ability (and clearly expressed intent) to sue Impax for patent infringement – is not changed in the old antibiotic

context. Prior to 1997, old antibiotics were exempt from the Hatch-Waxman provisions. 21 U.S.C. § 357 (1996). However, Section 357 was repealed by the Food and Drug Administration Modernization Act of 1997 (Modernization Act). Pub. L. No. 105-115 § 125(b)(1), 111 Stat. 2325 (1997) (Ex. N). Thus, under the current statutory framework, a claim for patent infringement under Section 271(e)(2) can be brought against old antibiotic ANDAs[6] (as Medicis concedes, Mot. at 6), which creates an actual infringement controversy between the parties.

Medicis also suggests that this case is different because the paragraph IV certification and 30-month stay provisions do not apply to old antibiotics.[7] (Mot. at 6-7.) Medicis erroneously equates injury-in-fact with (and only with) the 30-month stay in ANDA cases. While the 30-month stay may create injury-in-fact, it is not the only basis for justiciable injury in ANDA cases. For example, the Hatch-Waxman Act provides that a declaratory judgment action may be brought by an ANDA applicant even under circumstances where the ANDA is not subject to the 30-month stay.[8] 35 U.S.C. § 271(e)(5); *see also Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d

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[6] The plain language of the statutory provision creating the cause of action for infringement applies to all ANDAs and does not make any distinction about whether or not the ANDA involves old antibiotics. 35 U.S.C. § 271(e)(2). Accordingly, courts have held that ANDAs for old antibiotics are subject to infringement actions under Section 271(e)(2). *See Glaxo Group Ltd. v. Apotex, Inc*., 272 F. Supp. 2d 772, 779 (N.D. Ill. 2003) ("the court concludes, as it did before, that defendant's [old antibiotic] ANDA application triggered a violation of § 271(e)(2)"), *aff'd in part, rev'd in part on other grounds*, 376 F.3d 1339 (Fed. Cir. 2004); *Teva Pharms. USA, Inc. v. Abbott Labs*., 301 F. Supp. 2d 819, 830 (N.D. Ill. 2004) ("Teva's submission of an [old antibiotic] ANDA constituted an act of infringement sufficient to satisfy the second prong of the 'actual controversy' test") (citation omitted). Indeed, the Federal Circuit, the court with exclusive appellate jurisdiction over all patent cases, 28 U.S.C. § 1295(a)(1), upheld a finding of infringement under Section 271(e)(2) based on the filing of an ANDA for an old antibiotic. *Glaxo Group Ltd. v. Apotex, Inc*., 376 F.3d at 1344 & 1351.

[7] In a typical New Drug Application, applicable patents may be listed with the FDA in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1). When an ANDA is submitted for the same drug and the applicant concludes that the listed patents are invalid or not infringed, the applicant may provide notice of a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If a patent infringement suit is filed within 45 days of the notice, approval of the ANDA is stayed for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). While the Modernization Act excepted old antibiotic ANDAs from the paragraph IV certification and 30-month stay provisions, it nevertheless subjected old antibiotic ANDAs to the cause of action for patent infringement created by Section 271(e)(2). Pub. L. No. 105-115 § 125(d)(2)(A)(i), 111 Stat. 2327.

[8] If no patent infringement suit is filed within 45 days of receiving notice of a paragraph IV certification, then the 30-month stay is not applicable. 21 U.S.C. § 355(j)(5)(B)(iii). After the 45 days expire, the ANDA applicant may file an action for a declaratory judgment. 35 U.S.C. § 271(e)(5).

106, 111 (D.D.C. 2004), *aff'd*, 389 F.3d 1272 (D.C. Cir. 2004). Indeed, declaratory judgment jurisdiction has been found in cases specifically involving ANDAs for old antibiotics. *See Abbott Labs.*, 301 F. Supp. 2d 819.

Finally, Medicis argues that its numerous threats of patent litigation have caused no injury to Impax "because it has not obtained FDA approval to market its generic drug." (Mot. at 6.) This argument fundamentally misapprehends the role of Section 271(e)(2). As the Supreme Court explained, "the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The whole point of Section 271(e)(2) is to create an infringement controversy before the ANDA applicant has obtained FDA approval to market its generic drug.[9] *Novopharm*, 110 F.3d at 1569; *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006) ("purpose [of the Hatch-Waxman Act] is to permit the matter to be decided before the drug goes to market").

The dispute between Medicis and Impax arises because Medicis is accusing Impax of illegal activity (*i.e.*, infringement under Section 271(e)(2))[10] and Impax disputes that it has done anything improper. Declaratory judgment should be available to resolve the parties' dispute under such circumstances. *SanDisk*, 480 F.3d at 1381. By statute, Medicis has a justiciable claim for patent infringement against Impax. Consequently, Impax's corresponding declaratory judgment claim is likewise justiciable:

> It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party. In fact, the Supreme Court has stated: "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case."

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[9] Under Medicis's flawed reasoning, even if Medicis actually filed suit for infringement under Section 271(e)(2), Impax still would not have suffered injury and thus would be prevented from filing a counterclaim for declaratory judgment on the same patent. The Supreme Court has rejected such reasoning. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993).

[10] Although there are different remedies for patent infringement under Section 271(e)(2), *see* 35 U.S.C. §§ 271(e)(3)-(4), submission of an ANDA for a drug covered by an issued patent nevertheless constitutes a technical act of patent infringement.

Novartis, 482 F.3d at 1342 (*quoting Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Accordingly, there is a justiciable infringement controversy concerning whether Impax's ANDA infringes the '838 patent under Section 271(e)(2).

3. The Actual Controversy Between the Parties Is Confirmed By Medicis's Threats of Suing Generic Competitors

Medicis's threats of enforcing its '838 patent (*see* Section II.B, *supra*) constitute "a course of conduct that shows a preparedness and willingness to enforce its patent rights." *SanDisk*, 480 F.3d at 1382-83. By clearly conveying "its intent to assert its rights" under the '838 patent, Medicis has created an actual and justiciable controversy.[11] *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1370 (Fed. Cir. 2007).

The two unpublished district court cases upon which Medicis relies (Mot. at 7-8) are readily distinguishable. In *BridgeLux, Inc. v. Cree, Inc.*, there was no evidence that the patentee "has ever threatened BridgeLux with suit." No. C06-6495, 2007 WL 2022024, at *9 (N.D. Cal. July 9, 2007). That is plainly not the situation here, since Medicis threatened that it will "aggressively prosecute the patents" against generic competitors of Solodyn®. (Ex. I at 6.) Likewise, in *Prasco, LLC v. Medicis Pharmaceutical Corp.*, the declaratory plaintiff "cannot point to any statements by Defendants indicating that Defendants take a position that Prasco's OSCION product infringes the patents-in-suit." No. 1:06cv313, 2007 WL 1974951, at *3 (S.D. Ohio July 3, 2007), *on appeal*, No. 2007-1524 (Fed. Cir.). In this case, by contrast, Medicis

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[11] That Medicis has elected to delay filing its own patent infringement suit by moving to dismiss at this juncture does not detract from the immediacy of the present controversy. The Declaratory Judgment Act was intended to address situations like the present one, where the patentee "attempts extra-judicial patent enforcement" but "refused to grasp the nettle and sue." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988). Medicis should not be permitted to engage in forum shopping by moving to dismiss in this judicial district where Impax is headquartered (Compl. ¶ 1), only later to turn around and bring suit for patent infringement in a judicial district that is reputed to be friendlier to patentees. *See Micron*, 2008 WL 540182, at *3. Nor should Medicis be allowed to avoid the timely resolution of this infringement dispute but later claim irreparable injury or seek preliminary relief for Impax's alleged patent infringement.

Medicis's statements leave no doubt that it fully intends to "aggressively" bring suit on the '838 patent to protect its "flagship product." This infringement dispute should not be permitted to persist unresolved while Medicis deliberates over the most advantageous time and place to file suit. An actual controversy exists now and should be resolved.

has clearly taken the position that generic competitors of Solodyn® infringe the '838 patent, *see* Section II.B, *supra*, and Impax is the only such known generic competitor. (Ex. C at 15.)

The recent Federal Circuit case of *Micron Technology, Inc. v. MOSAID Technologies, Inc.* is more analogous to the facts of this case. Just as with Medicis, the patentee in *Micron* "issued public statements reiterating its intent to pursue" an "aggressive" patent strategy and that it would be "unrelenting in the assertion of [its] patent portfolio." 2008 WL 540182, at *1 (brackets in original). The Federal Circuit concluded that the patentee's public statements "confirm its intent to continue an aggressive litigation strategy," which was evidence that "amply supports a real and substantial dispute between these parties." *Id.* at *3.

4. Impax Has Suffered Injury-In-Fact that Can Be Redressed by Declaratory Judgment

Medicis's threats of patent infringement have created justiciable injury-in-fact that is redressable by a declaratory judgment. Medicis's attempt to myopically focus on the inapplicable 30-month stay (Mot. at 6) ignores other types of justiciable injury-in-fact that are present in this case.[12]

First, Impax's reasonable apprehension of suit is a justiciable injury-in-fact. Prior to the relaxation of justiciability standards by *MedImmune*, the Federal Circuit required declaratory judgment plaintiffs "to show a single type of Article III injury-in-fact, 'a reasonable apprehension of imminent suit.'" *Novartis*, 482 F.3d at 1340 (citation omitted). While a reasonable apprehension of suit is no longer necessary to show injury-in-fact, it certainly is still sufficient, having been the basis for injury-in-fact even under the older, more stringent test for justiciability. *SanDisk*, 480 F.3d at 1380-81. As the Federal Circuit has explained, the "threat of litigation is a present injury creating a justiciable controversy." *Novartis*, 482 F.3d at 1341 (emphasis added); *see also Cardinal Chem.*, 508 U.S. at 96 (If "a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim, under the [Declaratory Judgment] Act.")

[12] For example, justiciable injury-in-fact is routinely found in non-ANDA patent cases where the 30-month stay provisions are inapplicable. *See, e.g., Arrowhead Indus.*, 846 F.2d at 738-39.

(emphasis in original). Here, Medicis's public threats to sue generic competitors of Solodyn® for patent infringement more than suffice to demonstrate Impax's reasonable apprehension of suit. *See Micron*, 2008 WL 540182, at *4.

Medicis had an opportunity to dispel the infringement controversy by granting a covenant not to sue, but it failed to do so. (Compl. ¶ 12.) This refusal to provide a covenant not to sue underscores the risk of patent infringement litigation faced by Impax. *See Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 317 (S.D.N.Y. 2003).

Second, Impax is subject to justiciable injury-in-fact because its concrete economic interest in its ANDA application is impacted by Medicis's accusations of patent infringement. Injury-in-fact exists when a patentee's actions have "plac[ed] into actual dispute the soundness of [declaratory plaintiff's] ANDA and [its] ability to secure approval of the ANDA." *Novartis*, 482 F.3d at 1340. An ANDA is a substantial undertaking that requires chemical formulation of the generic drug product and documentation including bioequivalence studies and manufacturing information. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94. It is "a protracted and costly process of obtaining regulatory approval" that "illustrates the kind of 'concrete steps' or 'meaningful preparation' needed to establish an actual controversy." *Kos Pharms.*, 242 F. Supp. 2d at 318; *see also Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001) (filing and acceptance of an ANDA "means that [generic manufacturer] is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product"). Given the concrete interest in an ANDA application, a patent infringement dispute creates injury-in-fact because it "would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market." *Novartis*, 482 F.3d at 1344.

B. The Court Should Not Decline to Exercise Jurisdiction

"There must be well-founded reasons for declining to entertain a declaratory judgment action." *Capo*, 387 F.3d at 1357. When the "objectives for which the Declaratory Judgment Act was created" are served, discretionary dismissal is "rarely proper." *Micron*, 2008 WL 540182, at *4.

The purposes of the Declaratory Judgment Act are well-served by adjudicating Impax's claim for declaratory relief. First, Medicis has engaged in (indeed, its strategy is premised upon) "extra-judicial patent enforcement" tactics of the sort that led to the enactment of the Declaratory Judgment Act. *Capo*, 387 F.3d at 1357. By sending a "very strong message" that it will enforce the '838 patent (Ex. F at 13) but "refus[ing] to grasp the nettle and sue," Medicis creates "uncertainty and insecurity" in the business environment that is properly resolved by a declaratory judgment. *Micron*, 2008 WL 540182, at *4 (*quoting Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1346 (Fed. Cir. 2005)).

Second, because Medicis contends that generic competitors of Solodyn® infringe the '838 patent (Compl. ¶ 10), and Impax denies that any valid claims of the '838 patent are infringed (*id.* ¶¶ 13-14), the declaratory judgment should be adjudicated because it will "serve a useful purpose in clarifying and settling the legal relations in issue." *Capo*, 387 F.3d at 1357.

Finally, the public interest is served by adjudicating Impax's declaratory judgment action. "[P]atent rights are of competitive impact as well as innovation incentive," *id.* at 1358, and the public interest favors challenges to patents of dubious validity. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). This is particularly true in the present context, where "the public has a strong interest in obtaining generic drugs at the reduced rates that they are offered," and where the "principal purpose" of the Hatch-Waxman Act "was 'to increase competition in the drug industry by facilitating the approval of generic copies of drugs.'" *CollaGenex Pharms., Inc. v. IVAX Corp.*, 375 F. Supp. 2d 120, 141 (E.D.N.Y. 2005) (*quoting Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998)). Section 271(e)(2) was designed to "create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Novopharm*, 110 F.3d at 1569. Medicis should not be permitted to avoid prompt resolution of these issues that directly affect the public interest, when it has used the '838 patent to "send a very strong message" to deter generic competition.

Medicis chose to put its '838 patent at issue by announcing its position that the patent protects Solodyn® and that generic competitors will be sued for patent infringement. Impax concluded that no valid claims of the '838 patent cover its generic version of Solodyn® and

submitted an ANDA for this generic product. The parties thus have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Accordingly, the Court should exercise its jurisdiction and adjudicate Impax's declaratory judgment action.

IV. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court deny Medicis's motion to dismiss.

Dated: March 21, 2008

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